

K221539 GammaTileNov 9, 2022
166 days to decisionK221539 · Product code: **KXK** · Radiology
Source: <https://www.510kdatabase.net/k221539/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	May 27, 2022
Decision date	Nov 9, 2022
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gt Medical Technologies
Location	Tempe, AZ, US
Contact	Jessica Newhard
510(k) history	3 submissions · 3 cleared · 2019-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221539/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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